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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/566,180	01/18/2007	Bruno Balay	0512-1319	5568

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YOUNG & THOMPSON
209 Madison Street
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Alexandria, VA 22314

EXAMINER

MONTANO, MELISSA ANN

ART UNIT	PAPER NUMBER
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3738

NOTIFICATION DATE	DELIVERY MODE
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12/24/2009

ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

DocketingDept@young-thompson.com

Office Action Summary	Application No. 10/566,180	Applicant(s) BALAY ET AL.	
	Examiner MELISSA MONTANO	Art Unit 3738	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 22 October 2009.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-13 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-13 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 27 January 2006 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☒ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☒ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>1/27/2006</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Election/Restrictions

1. Applicant's election without traverse of Group I, claims 1-13, in the reply filed on 10/22/2009 is acknowledged. Claims 14-17 are canceled.

Oath/Declaration

2. The oath or declaration is defective. A new oath or declaration in compliance with 37 CFR 1.67(a) identifying this application by application number and filing date is required. See MPEP §§ 602.01 and 602.02.

The oath or declaration is defective because:
Non-initialed and/or non-dated alterations have been made to the oath or declaration. See 37 CFR 1.52(c).

The oath or declaration is defective because:
It appears as though the signature of inventor Michel-Henri Fessy is missing.

Claim Objections

3. Claim 6 is objected to because of the following informalities: Claim 6 recites the limitation "screw relief", which appears to be referring to the plurality of
-- screw reliefs --, as described in claim 1. Appropriate correction is required.

Claim Rejections - 35 USC § 112

4. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

5. Claims 1-13 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

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6. Claim 1 recites the limitation "the convex portions" in line 9. There is insufficient antecedent basis for this limitation in the claim.

7. Claim 1 recites the limitation "the outer surface" in line 10. There is insufficient antecedent basis for this limitation in the claim.

8. Claim 1 recites the limitation "the zones or troughs or recesses" in lines 10-11. There is insufficient antecedent basis for this limitation in the claim.

9. Claim 1 recites the limitation "the screw reliefs" in line 13. There is insufficient antecedent basis for this limitation in the claim.

10. Claim 6 recites the limitation "the sides of threads" in lines 5-6. There is insufficient antecedent basis for this limitation in the claim.

11. Claim 6 recites the limitation "the sponge-like bone" in 10. There is insufficient antecedent basis for this limitation in the claim.

12. Regarding claim 6, the phrase "that is to say" renders the claim indefinite because it is unclear whether the limitation(s) following the phrase are part of the claimed invention. See MPEP § 2173.05(d).

13. Claim 7 recites the limitation "the thread width" in lines 2-3. There is insufficient antecedent basis for this limitation in the claim.

14. Claim 7 recites the limitation "in a thread pitch, the proportion of the thread width, in the region of the trough, relative to the pitch, is from 0.2 to 0.5". The examiner is unsure what exactly is meant by this limitation and requests further clarification of the claim language in order to better convey what applicant is trying to claim.

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15. Claim 9 recites the limitation "the crests" in 2. There is insufficient antecedent basis for this limitation in the claim.

16. Claim 10 recites the limitation "the leading edge" in 2. There is insufficient antecedent basis for this limitation in the claim. The examiner notes that claim 10 may have been meant to depend from claim 9, rather than claim 1.

17. Claim 11 recites the limitation "the threading pitch" in 2. There is insufficient antecedent basis for this limitation in the claim.

18. Claim 12 recites the limitation "the cutting edges" in 4. There is insufficient antecedent basis for this limitation in the claim.

Claim Rejections - 35 USC § 103

19. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

20. Claims 1-8, 11, and 13 are rejected under 35 U.S.C. 103(a) as being unpatentable over US Patent No. 5,443,520 to Zweymuller et al. (Zweymuller) in view of US Patent Application No. 2003/0050705 A1 to Cueille et al. (Cueille).

Regarding at least claims 1-6

Zweymuller teaches a metal fixation element (screw-type cup; 10) for receiving a socket component (articular insert) of an artificial hip joint (abstract). The frontal region (12) and the first and second conically tapering walls (convex portions; 14, 16) are roughened on their outer surfaces particularly to facilitate biological fixation by

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osteointegration (col. 4, lines 13-18). The fixation element (10) also includes a self-tapping screw thread (screwing means; 52) comprising a plurality of teeth, the size, thickness, and height of which are adapted to the size of the socket component for use therewith according to Zweymuller (col. 4, lines 19-22), particularly shown within a tropical/equatorial zone (14) (fig. 4). Therefore, in both primary implantation and subsequent revision procedures, the operator, during surgery, can select a fixation element matched to the quality of bone material in the pelvic region. The figures of Zweymuller also show that the fixation element (10) include zones or troughs or recesses of threads (48).

However, Zweymuller does not explicitly teach the use of a coating.

Cueille teaches an acetabular cup for use in a total hip prosthesis comprising an inner bearing surface portion (21), an outer bone-interface layer (22) and a hydroxyapatite (HA) coating (23). The surface finish of the bone interface layer can be structured, by machining or any other method, before the HA coating is applied. Cueille also teaches that the hydroxyapatite coating is sprayed onto the porous surface (23) with a preferred thickness between 0.020 and 0.2 millimeters (20 and 200 micrometers) thick (page 2, paragraph 0023).

It is well known in the art that the acetabular cup/fixation element can be attached to the bone by a variety of attachment mechanisms, such as screws, a nut and bolt combination, pins, or threads on the cup. Adhesion and press fitting may also be used to affix the cup to bone. The cup may optionally include a textured bone-mating surface or appropriate coating (such as hydroxyl apatite) to encourage bone growth

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(see for example US Patent Application No. 2004/0199260 to Pope et al.). Therefore, it would have been obvious to one having ordinary skill in the art to modify the screw-type fixation element of Zweymuller to include a coating, particularly in portions of the cup that do not include the screw means/threads, since those areas would require more bone growth encouragement than the threads which already dig into the bone, as implicitly taught by Cueille.

Regarding at least claims 7, 11, and 13

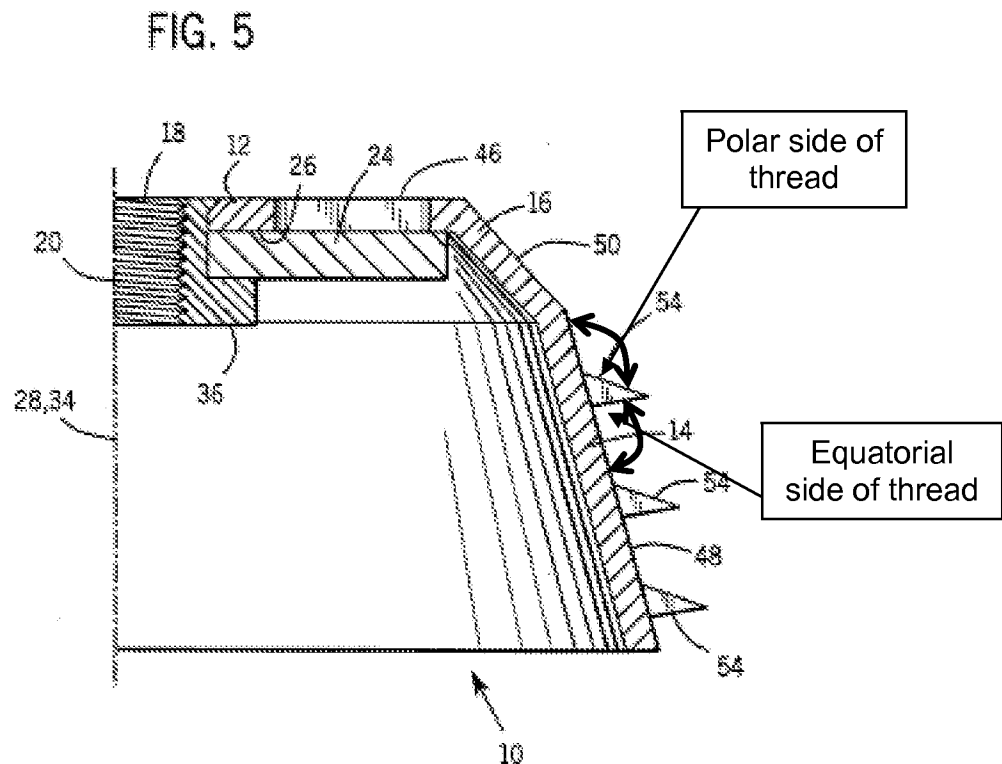
Zweymuller in view of Cueille teaches the invention substantially as claimed according to claim 6. Zweymuller further shows a regular and constant thread pitch, in which the proportion of the thread width in the region of the trough (48), relative to the pitch appears to be within the claimed range from 0.2 to 0.5. The examiner notes that thread pitch is defined as the distance from the top or peak of one thread to the top of the next. See figure below.

Regarding at least claim 8

Zweymuller in view of Cueille teaches the invention substantially as claimed according to claim 1. Though Zweymuller in view of Cueille does not explicitly teach angles of the threads with respect to the outer surface of the cup, Zweymuller does teach that the fixation element (10) includes a self-tapping screw thread (screwing means; 52) comprising a plurality of teeth (54), the size, thickness, and height of which

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are adapted to the size of the socket component for use (col. 4, lines 19-22). Therefore, in both primary implantation and subsequent revision procedures, the operator, during surgery, can select a fixation element matched to the quality of bone material in the pelvic region. Fig. 5 of Zweymuller appears to show that the cross-section of the threads is asymmetrical in a diametral plane, at least to the same extent applicant's is, with a smaller angle at the polar side of the thread and a greater angle at the equatorial side. See figure below.



It would have been obvious to one having ordinary skill in the art at the time of the invention to modify the invention of Zweymuller in view of Cueille to further include specifics about the threads, such as angles, in order to include a plurality of teeth (threads), the size, thickness, and height of which are adapted to the size of the socket

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component for use so that in both primary implantation and subsequent revision procedures, the operator, during surgery, can select a fixation element matched to the quality of bone material in the pelvic region, as taught by Zweymuller. It also would have been obvious to specify the angles of the threads on the polar side and on the equatorial side, particularly in view of the absence of any disclosed criticality of the claimed limitations. Further, it has been held that where the general conditions of a claim are disclosed in the prior art, discovering the optimum or workable ranges involves only routine skill in the art. *In re Aller*, 105 USPQ 233.

21. Claims 9-10 and 12 are rejected under 35 U.S.C. 103(a) as being unpatentable over Zweymuller in view of Cueille as applied to claim 1 above, and further in view of US Patent No. 5,147,407 to Tager (Tager).

Zweymuller in view of Cueille teaches the invention substantially as claimed according to claim 1. However, Zweymuller in view of Cueille does not teach that the crests of threads are relieved or that the leading edge is inclined.

Tager teaches a prosthetic cup member having an outer surface with coaxial threads interrupted by grooves extending transversely to the thread. The threads are self-tapping threads and are formed to permit the threaded outer shell to be screwed into the bone (abstract). Tager further teaches that openings (inclined grooves; 11) are milled at an angle with respect to the axis and at an angle with respect to the radius, i.e. the walls of the openings are inclined towards the rotational direction of outer shell (10) (col. 3, lines 1-9). The discrete thread portions (12) form a plurality of rows (zones; 13) at an angle to the axis of outer shell (10) between openings (11). Since the device

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taught by Tager is made in the same way as applicant's, it is inherent that it also includes crests with leading edges of threads that are radially higher than the remainder of the crest, and which leading edges are themselves inclined by being formed by a milling pass, as claimed by applicant.

It would have been obvious to one having ordinary skill in the art at the time of the invention to modify the invention of Zweymuller in view of Cueille to include crests of threads that are relieved or that the leading edge is inclined in order to facilitate insertion of the cup and improve its anchoring after emplacement, as taught by Tager (col. 2, lines 14-20).

Conclusion

22. Any inquiry concerning this communication or earlier communications from the examiner should be directed to MELISSA MONTANO whose telephone number is (571)270-5785. The examiner can normally be reached on Monday-Friday 8:00AM-5:00PM EDT.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Corrine McDermott can be reached on (571)272-4754. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only.

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For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

MM

/Bruce E Snow/
Primary Examiner, Art Unit 3738